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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,510	11/08/2001	Charles S. Schasteen	NVI 5183.1	9657

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SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,510	SCHASTEEN ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- *If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.*
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30,113-119 and 136-152* is/are pending in the application.

4a) Of the above claim(s) *144 and 145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,113-119,136-143 and 146-152* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. This Office action is responsive to Applicant's amendments and response filed September 15, 2004. Claims 1,9, 113,136-140, 146 and 148 have been amended. Claims 149-152 have been added.

Objections/Rejection Withdrawn

2. In view of Applicant's amendment and remarks the following objections/rejections are withdrawn:

a) objection to the specification, page 4, paragraph 5.
b) objection to the specification, page 4, paragraph 6.
c) rejection of claims 136-143 under 35 U.S.C. 112, second paragraph, page 5, paragraph 7.

Rejections Maintained

3. The rejection is maintained for claims 1-22, 29-30, 113-119, 136-141, 146-148 and newly added claims 149-152 under 35 U.S.C. 102(b) as anticipated by Conkle et al, for the reasons set forth on pages 1-9, paragraph 8 of the previous Office Action.

The rejection was on the grounds that Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8). Claim limitations such as "the composition ameliorates a decline or decrease in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and

amount determined by storage high-life determinations" are being viewed as inherent and as a limitation of intended use. The package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. If there is no novelty in a composition itself, then a patent cannot be properly granted on the composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The polypeptides of the claimed articles remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in composition constitute an "intended use" for that composition. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the claims are drawn to a composition which comprises oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly *no functional relationship exists between the instructions for use and the composition.* Thus, the instructions on the package insert bears no patentable weight with regard to

double patenting, 102, and 103 rejections. The claim limitation "wherein said oocysts have been separated by tangential flow filtration from an aqueous sporulation medium is a process limitation. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Conkle et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that claim 1, 9 and 10 have been amended to recite a composition for the prevention or control of coccidiosis comprising viable non-attenuated sporulated oocysts. Applicant urges that Conkle et al do not indicate what type of oocysts are used. Applicant urges that Conkle et al do not describe the use of non-attenuated oocysts. Applicant urges that Conkle et al do not teach a kit comprising the claimed composition. Applicant urges that the instructions in the kit of claim 113 constitute more than a mere intended use, they

are functionally related to the composition and therefore should be given patentable weight. Applicant urges that the Office has misinterpret claims 23 and 142. Applicant urges that claims 23 and 142 are directed to compositions which further comprise as a component thereof, a composition which ameliorates a decline or decrease in post-challenge performance. Applicant urges that the phrase "which ameliorates a decrease (or decline) in post-challenge performance" does not specify a mere property of the composition as a whole, but instead defines an additional component of that composition by a functional characteristic which that component characteristic possesses. Applicant urges that the Office has provided not evidence to support its states conclusion that the claim limitation "the composition ameliorate a decline or decrease in post –challenge performance" is inherent in the teachings of the prior art. Applicant urges that the Office has provided not evidence to support its states conclusion that the claim limitation "a ratio is defined by the minimum immunizing dose and amount determined by storage half-determinations" is inherent in the teachings of the prior art. Applicant urges that as amended claim 146 and 147 recites that "... the oocysts have been separated by tangential flow filtration from an aqueous sporulation medium using a filter membrane with a pore size such that sporulated oocysts cannot enter the pores, but bacteria can pass through the pores" and Conkle et al makes no statement or suggestion that the pore size should large enough for the passage of bacteria.

Applicant's arguments filed September 15, 2004 have been fully considered but they are not persuasive. The claims are directed to composition

comprising non-attenuated sporulated oocysts (a product). Conkle et al teach compositions comprising sporulated oocysts (see the Abstract). Conkle et al teach that the encysted protozoa which includes cysts and oocysts may be obtained from various sources including purified suspensions, intestinal lings and fecal suspensions (page 4). Therefore, the prior art teaches oocysts that are encompassed by the term "non-attenuated" as recited in the amended claims.

To address Applicant's comments regarding a kit, it should be noted that the kit as set forth in claim 113 comprises a composition containing sterile, viable sporulated oocysts and instructions for the administration of said composition to an animal. Conkle et al teach compositions comprising sporulated oocysts and further teach that the oocysts can be combined into a single sterile concentrate to be used in a single vaccine. Conkle et al also teach that combined concentrates are subject to filling and packaging under sterile conditions and a vaccine is produced (page 9). It should be noted that the instructions as to how to use the kit is a limitation of intended use and has no functional relatedness to the composition. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

To address Applicant's comment's regarding, "... a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" would be inherent in the teachings of the prior art because Conkle et al teach that encysted protozoa oocysts including *Eimeria maxima, E. mitis, E. tenella, E. acevulina, E. brumetti, E. necatrix, E. praecox* and mixtures thereof including multiple strains can be give in a single vaccine. Vaccines are known as pharmaceutical compositions that are used to immunize subjects and are thereby given in immunizing doses and can include determination by storage half-life determinations. Therefore, this claim limitation is met by the prior art.

To address Applicant's comments regarding the use of tangential filtration as recited in amended claim 146 to separate oocysts from an aqueous sporulation medium, it should be noted the claims are directed to a product and not a process. "tangential filtration" and "...using a membrane with a pore size such that sporulated oocysts cannot enter the pores, but bacteria can pass through the pores" are process limitations in a product claim. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or

property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Applicant has provided no side-by-side comparison to show that the claimed compositions differs from that of the prior art.

4. The rejection is maintained for claims 1-30, 113-119, 136-143, 146-148 and newly added claims 149-152 under 35 U.S.C. 103(a) as anticipated by Conkle et al in view of Brown et al for the reasons set forth on pages 9-12, paragraph 9 of the previous Office Action.

The rejection was on the grounds that Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8).

Conkle et al do not teach the use of *Propionibacterium acnes*.

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21). Brown et al teach that the amount of *Propionibacterium acnes* in the composition is about 0.5 mg to about 10 mg dried weight per milliliter of diluent (column 4, lines 15-21). Brown et al teach that other materials such as antibiotic, for example gentamicin may be added to the composition comprising *Propionibacterium acnes* (column 4, lines 7-14). Claim limitations such as, "a kit", "the composition ameliorates a decline in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as limitations of intended use. The claims limitation "wherein said composition contains at least about 30 milligrams (dry

weight of *P. acnes* per milliliter is being viewed as a limitation of optimizing experimental parameters since Brown et al teach that other initial concentrations of *P. acnes* suspension are within the scope of the invention because the actual administration to the chick is adjusted and diluted for optimum dosages (column 4, lines 19-22). The claim limitation "wherein said oocysts have been separated by tangential flow filtration from an aqueous sporulation medium is a process limitation. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the compositions comprising oocysts from the genus *Eimeria* of Conkle et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases. It would be expected barring evidence to the contrary that a composition comprising sporulated oocysts, a diluent, a buffer and a bactericide would be effective in preventing coccidiosis in animals.

Applicant urges that for a 103(a) rejection there must be: (1) some suggestion or motivation to combine the references, (2) a reasonable expectation of success and (3) the prior art must teach or suggest all claim limitations. Applicant urges that Conkle et al do not teach or suggest non-~~sporulated~~ attenuated ooysts. Applicant urges that if one were to add a composition comprising *P. acnes* in diluent as taught by Brown et al to the sporulated oocysts of Conkle et al this

combination would not satisfy all the limitations in the claimed invention. Applicant urges that Conkle et al and Brown et al as combined do not suggest compositions or kits for the prevention or control of coccidiosis comprising viable non-attenuated sporulated oocysts.

Applicant's arguments filed September 15, 2004 have been fully considered but they are not persuasive. Conkle et al teach compositions comprising oocysts that may be obtained from various sources including purified suspensions, intestinal linings and fecal suspensions (page 4). Therefore, the prior art teaches oocysts that are encompassed by the term non-attenuated. Conkle et al do not teach *Propionibacterium acnes.* However, Brown et al teach compositions comprising *P. acnes.* One of ordinary skill in the art would be motivated to add the *P. acnes* compositions as taught by Brown et al to the compositions comprising sporulated oocysts of Conkle et al because Brown et al teach *Propionibacterium acnes* is an immunostimulant for providing non-specific cell-mediated immune response in poultry (column 3). One of ordinary skill in the art would expect a reasonable expectation of success in using the compositions of Brown et al and Conkle et al as combined because Brown et al teach that *P. acnes* can be used to combat coccidiosis at an age as early as one or even *in ovo* and other poultry diseases and Conkle et al teach that the sporulated oocysts of the invention can be formulated into a vaccine against avian coccidiosis. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-30, 113-119, 136-143 and 146-152 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.* The amendment filed September 15, 2004 introduced new matter into the claims.

The claims have been amended to recite, "...non-attenuated sporulated oocysts ...". 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added limitation "non-attenuated" is not supported by the original disclosure. The instant disclosure states that "oocysts used in the practice of the invention can be obtained from a variety of sources" (page 11). The instant disclosure merely states that "the oocysts of the present invention are derived from wild-type oocysts" (page 11). The phrase "derived from wild-type oocysts" is broad and can encompass attenuated as well as non-attenuated oocysts". There is no disclosure in the instant specification that recites "non-attenuated sporulated oocysts". Therefore the recitation of "non-

attenuated sporulated oocysts" is considered to be new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

Status of Claims

6. No claims allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
December 20, 2004

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600